REMARKS

Following entry of the amendments presented above, claims 1-12 and 14-15 will be pending in the application. Claims 1 and 14-15 have been amended and claims 13 and 16-20 have been canceled without prejudice or disclaimer. The claim amendments are fully supported by the specification.

In the April 20, 2005 office action, claims 1 and 13-18 were rejected under 35 USC § § 102(a) and (e) as anticipated by Elliott. Claim 1 was rejected under § 102(b) as anticipated by Boom. Claims 1 and 16-20 were rejected under § 102(b) as anticipated by Fomovskaia. Claims 2-12 were rejected under 35 USC § 103(a) as obvious over Elliott in view of Swanson and Rieck. The specific grounds for response, and applicants response thereto, are set forth in detail below.

Support for claim amendments

The amendment to claim 1 is supported throughout the specification which makes it clear that the methods of the invention surprisingly can be used to extract DNA from hair that contains no hair root. See, for example, Example 1, at page 9 of the specification.

Claim Interpretation

The Examiner asserts that, under the definitions set forth in the specification, a surfactant such as Triton X100 or a detergent such as SDS meets the definition of a "stabilizing agent." The Examiner further asserts that potassium iodide meets the definition of a "buffering agent." Applicants respectfully disagree as neither the specification nor common scientific usage supports the Examiner's assertions.

As the Examiner correctly states, the claim should be given its broadest reasonable interpretation. MPEP § 2111. However, the broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *Id. See also In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). Nothing in the specification supports the notion that surfactants or detergents would be understood by one skilled in the art as stabilizing agents. The specification of the instant application defines a stabilizing agent thus:

> The stabilizing agent is a reagent that stabilizes the solution and that applicants believe, without being bound by theory, stabilizes the DNA that is extracted from the source tissue or material. The stabilizing agent can be, for example, sodium metasilicate, sodium silicate, sodium sesquisilicate, sodium aluminosilicate, sodium fluorosilicate, and can be present at a concentration of about 1 mM to about 500 mM, typically 1-100 mM, and advantageously about 25 mM.

Nothing in this definition would lead one skilled in the art to the conclusion that any surfactant or detergent would stabilize DNA extracted from a source tissue, such as hair as defined in amended claim 1. Furthermore, the Examiner fails to provide any explanation as to why one skilled in the art would regard surfactants or detergents as DNA stabilizing agents in the context of the present invention or, indeed, in any context. It is notable that the stabilizing agents exemplified in the specification, such as alkaline metal silicates, are neither surfactants nor detergents, and do not remotely resemble surfactants such as Triton X100 or detergents such as SDS. Accordingly, the Examiner's assertion that "stabilizing agent" should be interpreted to encompass surfactants and detergents is unreasonable and should be withdrawn.

The specification of the instant application defines a buffering agent thus:

> The buffering agent that optionally is present may be any agent that can act as a pH buffer. Such agents are well known in the art and include tetrasodium pyrophosphate, sodium citrate, sodium carbonate, trisodium nitrilotriacetic acid, sodium fluoroborate, sodium borate, and sodium triphosphate. The buffering agent can be present at a concentration of 0-500 mM, typically 1-200 mM, and advantageously at about 25-150 mM.

By contrast, potassium iodide has no buffering capacity whatsoever and therefore cannot be considered a "buffering agent" under any reasonable interpretation. Accordingly, the Examiner's assertion that "buffering agent" should be interpreted to encompass potassium iodide is unreasonable and should be withdrawn.

In summary, it is the Examiner's burden to demonstrate that the claim interpretation used in the office action is reasonable. For the reasons set forth above, applicants respectfully submit that neither a surfactant nor a detergent can reasonable be interpreted to be stabilizing agents, nor can potassium iodide reasonably be interpreted as a buffering agent. Absent competent evidence to the contrary, the Examiner's claim interpretations should be withdrawn.

Rejections under 35 USC § 102

Claims 1 and 13-18 are rejected under 35 USC §§ 102(a) and (e) as anticipated by Elliott. Claim 1 is rejected under § 102(b) as anticipated by Boom. Claims 1 and 16-20 are rejected under § 102(b) as anticipated by Fomovskaia. Applicants respectfully traverse.

It is axiomatic that, for a prior art reference to be anticipatory, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). None of the cited references describes every element of the claimed invention and, accordingly, cannot anticipate the claimed invention.

Elliott

The instant claims describe a method that uses a highly basic solution, which is defined in the specification thus:

> In the context of the present invention, a highly basic solution is a solution having a pH of at least 12, and advantageously having a pH of at least about 13.

By contrast, the solution described by Elliott has a pH of 8, which is barely basic at all, let alone highly basic, and which clearly does not meet the definition of "highly basic" as that term is used in the instant application. Accordingly, Elliott does not describe each and every element of the claimed invention and the rejection should be withdrawn.

Boom

The buffers described by Boom have a pH no higher than 8 (lysis buffer L6 cited by the Examiner has a pH of 8.0). Accordingly, Boom does not describe a method using a solution that is highly basic and fails to describe each and every element of the claimed invention. Moreover, Boom does not describe isolation of DNA from hair, and for this further reason, fails to describe each and every element of the claimed invention. Accordingly, applicants respectfully submit that the rejection should be withdrawn.

Fomovskaia

The buffers described by Fomovskaia have a pH no higher than 8 and, are in fact, described by Fomovskaia as containing a "weak base" (see page 10, four lines from bottom of page). Accordingly, Fomovskaia does not describe a method using a solution that is highly basic and fails to describe each and every element of the claimed invention. Moreover, Fomovskaia does not describe isolation of DNA from hair, and for this further reason, fails to describe each and every element of the claimed invention.

In addition, the Examiner asserts that the SDS used by Fomovskaia is a "stabilizing agent" in the context of the present invention. Applicants respectfully disagree with this definition for the reasons set forth above and further note that Fomovskaia describes SDS as a "denaturing agent."

> More specifically, the chemical coating solution includes a protein denaturing agent and a free radical trap. The denaturing reagent can be a surfactant that will denature proteins and the majority of any pathogenic organisms in the sample. Anionic detergents are examples of such denaturing reagents. The chemical solution can include a weak base, a chelating agent, and the anionic surfactant or detergent, and optionally uric acid and urate salt as discussed in detail in the above-cited U.S. Pat. No. 5,807,527. More preferably, the sneak base can be a Tris, trishydroxymethyl methane, either as a free base or as the carbonate, and the chelating agent can be EDTA, and the anionic detergent can be sodium dodecyl sulfate. Other coatings having similar function can also be utilized in accordance with the present invention.

See page 10, last paragraph (emphasis added). Applicants respectfully submit that one skilled in the art would not reasonably consider SDS to be simultaneously a "stabilizing agent" and a "denaturing agent."

For the reasons set forth above, applicants respectfully submit that Fomovskaia fails to describe each and every element of the claimed invention and the rejection should be withdrawn.

Rejection under 35 USC § 103

Claims 2-12 are rejected under 35 USC § 103(a) as obvious over Elliott in view of Swanson and Rieck. Specifically, the Examiner asserts that Elliott teaches a method for extracting DNA from a biological sample using a highly basic solution containing a chelating

agent, a stabilizing agent and a buffering agent. The Examiner concedes that Elliott does not teach alkali metal gluconates as chelating agents or silicates as stabilizing agents, but asserts that this deficiency is remedied by Swanson, which allegedly teaches use of solutions containing these materials for depilating hair. Rieck is cited as teaching use of sodium silicates as washing agents. Applicants respectfully traverse.

All claims are presumed initially to be non-obvious. A *prima facie* case of obviousness requires three elements: (1) a teaching or suggestion of all of the claim limitations; (2) a suggestion or motivation to modify or combine the teachings of the applied prior art; and (3) a reasonable expectation of success in reaching the claimed invention. The Examiner bears the initial burden of supporting any *prima facie* assertion of obviousness with adequate facts. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). See MPEP § 2142. The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the reference must expressly or impliedly suggest the claimed invention, or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). MPEP § 2142. The Examiner's allegations regarding the cited references fail to meet this test and, accordingly, the rejection should be withdrawn.

As an initial matter, Elliott fails to teach or suggest methods of extracting DNA from hair lacking a hair root, and fails to teach or suggest using a highly basic solution, as described above. Hair roots contain epithelial cells which are the source of the DNA obtained in the Elliott methods (see column 1, lines 40-49 of Elliott), whereas hair containing no root is made up primarily of the protein keratin, and lacks the root cells. This is why Elliott specifically teaches that the hair must contain a root (see title and abstract, and claim 1). Accordingly, by specifying that the hair must contain a root as a source of cells, Elliott teaches away from the present invention.

Swanson is a method of depilating hair from animal carcasses. By definition, therefore, the hair used by Swanson contains hair roots. Rieck merely describes use of sodium silicates for softening water. Neither Swanson nor Rieck has anything to do with extracting DNA. The

combination of references cited by the Examiner therefore fails to teach or suggest a method of extracting DNA from hair containing no hair root. Accordingly the combination of references fail to teach or suggest all of the claim limitations of claim 1 and no *prima facie* case of obviousness exists and the rejection should be withdrawn

The rejection also fails to meet the second test for a *prima facie* case of obviousness because there is no motivation to combine the cited references. Elliott is directed to methods of extracting DNA from hair root, while Swanson is directed chiefly to methods of removing hair from animal carcasses and providing denatured protein for animal feed. Rieck is concerned with softening water and contains no reference to DNA or hair at all.

The Examiner's stated rationale for combining these disparate references is that it would have been obvious to modify Elliott's methods of obtaining DNA from hair roots by including alkali metals as allegedly taught by Swenson and Rieck for promoting alkaline lysis and recovery of protein in alkaline solution. The Examiner fails, however, to explain why one skilled in the art would have been motivated to modify the methods of Elliott by looking to Swenson, which has nothing to do with DNA, let alone with recovering DNA from hair containing no root, and is at most peripherally directed to recovery of denatured protein for use in animal feed. The Examiner's assertions regarding the teachings of Swenson with regard to recovery of protein are irrelevant to the claimed invention, which is directed to methods for obtaining DNA, not protein, from hair containing no root. Moreover, the methods described by Swanson are carried out at high temperature under conditions that one of ordinary skill in the art would understand would be unlikely to provide any intact DNA. Accordingly, there would have been no motivation to combine the cited references, which are directed to wholly disparate methods, and no *prima facie* case of obviousness exists and the rejection should be withdrawn.

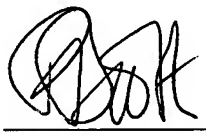
Finally, the Examiner alleges that one of ordinary skill in the art would have had a reasonable expectation of success in combining the references because modifying Elliott's methods of DNA extraction using the agents taught by Swanson and Rieck "would result in a highly alkaline solution that would aid in alkaline lysis of DNA in a biological sample." Applicants respectfully submit that alkaline lysis of DNA would be highly undesirable in the context of the present invention, which is directed to methods of extracting DNA, and not lysed

DNA, from hair containing no root. Accordingly, there would have been no reasonable expectation of success in combining the cited references, and the rejection should be withdrawn.

CONCLUSION

In view of the above amendment and remarks, applicants respectfully request that all objections and rejections be withdrawn and that a notice of allowance be forthcoming. The Examiner is invited to contact the undersigned attorney for applicants at 202-912-2197 for any reason related to the advancement of this case.

Respectfully submitted,



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